Medisafe®

PICO evo®

User Manual

Rev.C

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Section 1: Introduction

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Note to Person Installing this Product
This Memorandum of Registration MUST be completed by the person undertaking installation and witnessed by the person responsible for this product.

Note to Owner of this Product
Be sure that this Memorandum of Registration is completed by the person undertaking to install the product. In the event of a Warranty Claim the information contained within this Registration is your evidence that the product has been correctly installed.

Important Note:
Failure to provide this evidence in the event of a warranty claim may result in the claim being rejected (this does not affect your statutory rights as a customer).

Owner's Name:

Installation Address:

Installation Date:

Product type

Auto Dosing Facility:

☐ Yes ☐ No

Serial Number:

Software Version:

Installed by:

Witnessed by:

Service and Maintenance Requirements:
This product should be serviced on a regular basis to ensure that the product continues to perform within the guidelines recommended by your local/national washing/disinfection Periodic Testing regime.

If this symbol appears on equipment then the documentation must be consulted in all cases where symbol 14 of table 1 (caution) is marked, in order to find out the nature of the potential hazard and any actions which have to be taken to avoid them.

Warning

This symbol alertes you to situations that may cause serious body harm, death or property damage.

Caution

This symbol alerts you to situation that may cause body injury or property damage.

Warning

This symbol indicates the presence of electric shock hazards. Dangerously high voltages are present inside the product. Do not remove the outer casing. Refer servicing and repair to qualified personnel only.

Important Note

This symbol indicates that “Important Note(s)” are manufacturer recomendation.

This marking indicates that this product should not be disposed with Municipal wastes throughout the EU. To prevent possible harm to the environment or human health from uncontrolled waste disposal, recycle it responsibly to promote the sustainable reuse of material resources. In accordance with European Directive WEEE 2002/96/EC, please contat your local recycling authorities for collection centers to deliver waste electrical and electronic equipment or the equipment can also be handed over to a Medisafe distributor when purchasing a new washer disinfector.

Electrical

This product operates from mains electricity and is supplied with the correct connector for the market into which it is sold. If the supplied connector is removed during installation, be sure to observe the correct colour code when reconnecting to an appropriate plug or fused spur.

Warning

Dangerously high voltages are present inside the product. Do not remove the outer casing. Refer servicing and repair to qualified personnel only.

Warning

To prevent fire or shock hazard, do not expose this product to rain or moisture.

Heat

The effective operation of this product relies on water being heated to elevated temperatures which may cause scalding if care is not taken during operation. Although the automatic door locking system will assist in preventing such injuries, care must be taken when loading and unloading instruments after a cycle has been completed.

Warning

Water temperature within the wash chamber may exceed 85^{O}C during and after operation. Take care when removing items on completion of a cycle and allow good time for the items to cool to a safe temperature before handling.

Decontamination

This product MUST be decontaminated in accordance with local regulations before transportation. In the event that the product must be returned to the supplier, it is vital that the Decontamination Certificate on page 40 of this manual is completed and returned with the product.

Chemicals

Only Medisafe detergents and additives are approved and recommended for use in this product. Using non-approved chemicals may cause damage to the product and could void both your warranty and your guarantee of performance.

Door Release

For your protection, the loading door is fitted with an electric safety locking system and can not be operated unless the product is connected to a mains power supply. An override facility exists which allows the door to be opened manually in an emergency or if power to the product becomes interrupted. A special key is provided for this purpose.

Installation and Maintenance

This product has been factory tested to ensure that it performs according to its design parameters. It is essential that the correct installation procedure is adhered to and that the recommended regular maintenance checks are performed to ensure that it continues to operate within design parameters.

User must read this message prior to any chemical handling

Chemical Safety Note

- An emergency guideline wall chart of the chemical used in machine must be displayed near the machine.
- Do not use or handle any chemical until you have read and understood the label and the Material Safety Data Sheet (MSDS) for that chemical.
- In case of any body contact with chemical, always follow emergency procedure given in that particular chemical's MSDS or call emergency services.
- Use plastic gloves when handling any chemical.
- Goggles or full face visor to be worn when working with detergent or chemicals.
- It is recommended to wear a plastic disposable apron.
- Use funnel whenever transferring any chemical from one container to another.
- Always follow MSDS instructions for safe disposal of chemical container.

The owner of this equipment has the responsibility for giving training and keeping records of training to the user.

The following table can be used for keeping training records

Date	Name	Signature

The PICO evo. Washer Disinfector

The PICO evo. range of washer disinfectors have been designed to clean various surgical instruments, implements, and associated products used within a medical environment. This objective is achieved through separate wash and disinfection stages of an automatic cycle. Optimum decontamination is ensured though the use of sophisticated electronics which control and monitor the entire cycle without any need for user input.

If a wash/disinfect cycle fails to achieve any one of the predetermined parameters then the system reports a failed cycle. The unit registers such a failure and brings it to the attention of the operator, who is then unable to remove the load without being aware that the cycle has been aborted.

General Wash

The PICO evo. is primarily intended to wash and disinfect general medical instruments which are placed within a range of removable baskets. A rotating spray arm distributes fluid evenly over the load.

Lumen Wash

As well as a rotating spray arm, the PICO evo. adds the facility to wash and disinfect the inside of lumen devices such as dental hanpieces which are connected on high pressure handpiece manifold.

Auto Dosing

All PICO evo. models are supported by Automatic Dosing System, which introduces a controlled amount of detergent from an external container during the appropriate stage(s) of a wash cycle.

Washing

Washing is achieved using unique, specially formulated and clinically validated detergents which are introduced into the cycle during the operating cycle to clean away fat, protein, starch, body fluid residue, etc. The detergent (3EZyme or Medisafe PH safe) is dispensed just before the wash cycle by automatic measured dispensing system into the chamber from an external container.

Important Note:

It is vital that the correct programme is chosen according to the detergent being used. Details can be found in Section 3-4.

Disinfecting

Effective thermal disinfection is achieved by raising the temperature of the final rinse water within the wash chamber to a predetermined level, and then maintaining this temperature for a period of time specifically identified as being acceptable by international decontamination standards.

Drying

Drying is achieved by forced hot air circulation within the chamber to remove residual moisture from the instruments and hand piece channels leaving the instrument load dry and ready for the sterilisation process.

Scale Inhibitor

To improve cleaning performance, and to help reduce scaling during thermal disinfection, a de-scaling additive (AWT Fluid) is automatically introduced into the cycle. This helps to ensure that the unit maintains optimum performance throughout its operational life.

Compliance

All variants in the PICO evo range have been designed to perform within the guidelines recommended by international decontamination Standards. A stringent quality control programme ensures that every unit is manufactured and tested under controlled conditions to ensure that all products perform identically.

Declaration of CE Conformity

The PICO evo range is designed and manufactured in the UK by Medisafe UK Ltd. and complies with the essential requirements of the Medical Devices Directive 93/42/EEC (where appropriate). All products are CE compliant and are registered as Class IIa devices through the application of all 18 rules within Annex IX of the Medical Devices Directive 93/42/EEC.

CE 0473

Environmental Policy

Waste electrical and electronic products must not be disposed of with household waste. Please recycle where facilities exist. Check with your Local Authority or Distributor for recycling advice.

Manufacturer Information:

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PICO evo®

Section 2: Installation

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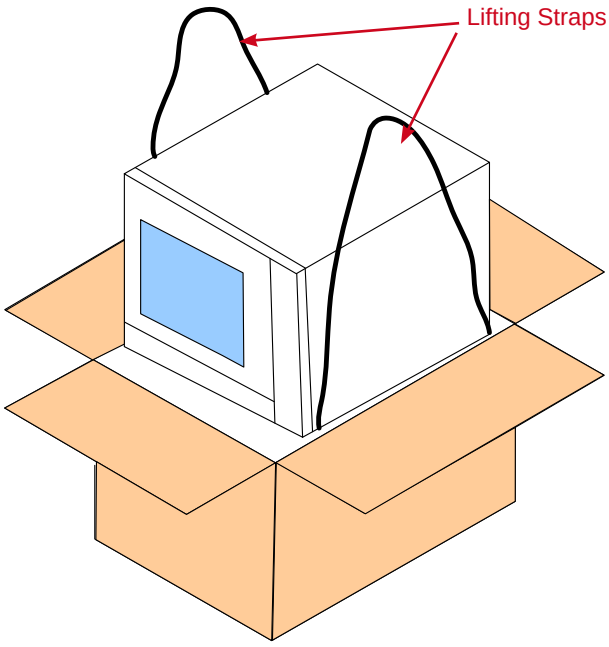
Caution:
EXCESSIVE WEIGHT HAZARD
To avoid back or other injury, have two persons to lift the washer by using the straps as shown in the picture below.



Carefully open the carton and with the help of two persons lift the machine by using “lifting Straps” to take out the machine. Please note that in order to lift the machine without lifting straps, the feet must be adjusted to 25mm height. Please retain the carton and all packaging materials. If it needs to be returned to the supplier for any reason then the original carton and packaging materials should be re-used.

Important Note
This product must be connected to a suitable mains power supply to enable the loading door to be released.

Connect product to a mains power supply and open door by pressing Door Release button. Remove basket and accessory pack (see important note above).

Your PICO evo has been despatched with a range of accessories to enable easy installation and efficient operation. Their use is detailed throughout this manual. Ensure that all these items are present before attempting to install or operate the unit. Complete the following Enclosures Check List and notify your supplier of any shortages or damaged components as soon as possible.

Enclosures Check List

- 1 Gray drain hose
- 1 Blue cold water hose
- 1 Red Hot Water hose
- 1 Carrier system with divider
- 1 Tray c/w Manifold
- 1 Instrument Trays
- 1 Rack System
- 1 Dental Burr Basket
- 1 RS232 data (printer) lead
- 1 Door Release Probe
- 1 Owner’s Manual
- 1 Bottle 3E-Zyme detergent
- 1 Bottle AWT Fluid
- 1 Chemical-pick-up tube
- 1 AWT (de-scaler) pick-up tube
- Routine Check Log Book (UK Only)

Printer
Printer and Medi-Logger is not supplied but may be purchased as an approved accessory from your supplier using the following code:

Printer & Power supply:	MED1014
Thermal paper rolls:	MED1014.1
Medi-logger:	M20070G

Detergents and Water Treatment Fluid
Packs of approved detergent and bottles of water treatment fluid may be purchased from your supplier using the following codes.

3E-Zyme:	MED8035 (1 x 4 Litre bottle)
AWT Fluid:	MED1000.09 (4 x 0.5 Litre bottles)

Important Note:
Using non-approved chemicals, accessories, and replacement parts may cause damage to this product and could result in disputed warranty claims. Please read safety instructions before using any chemical on section 1-4.

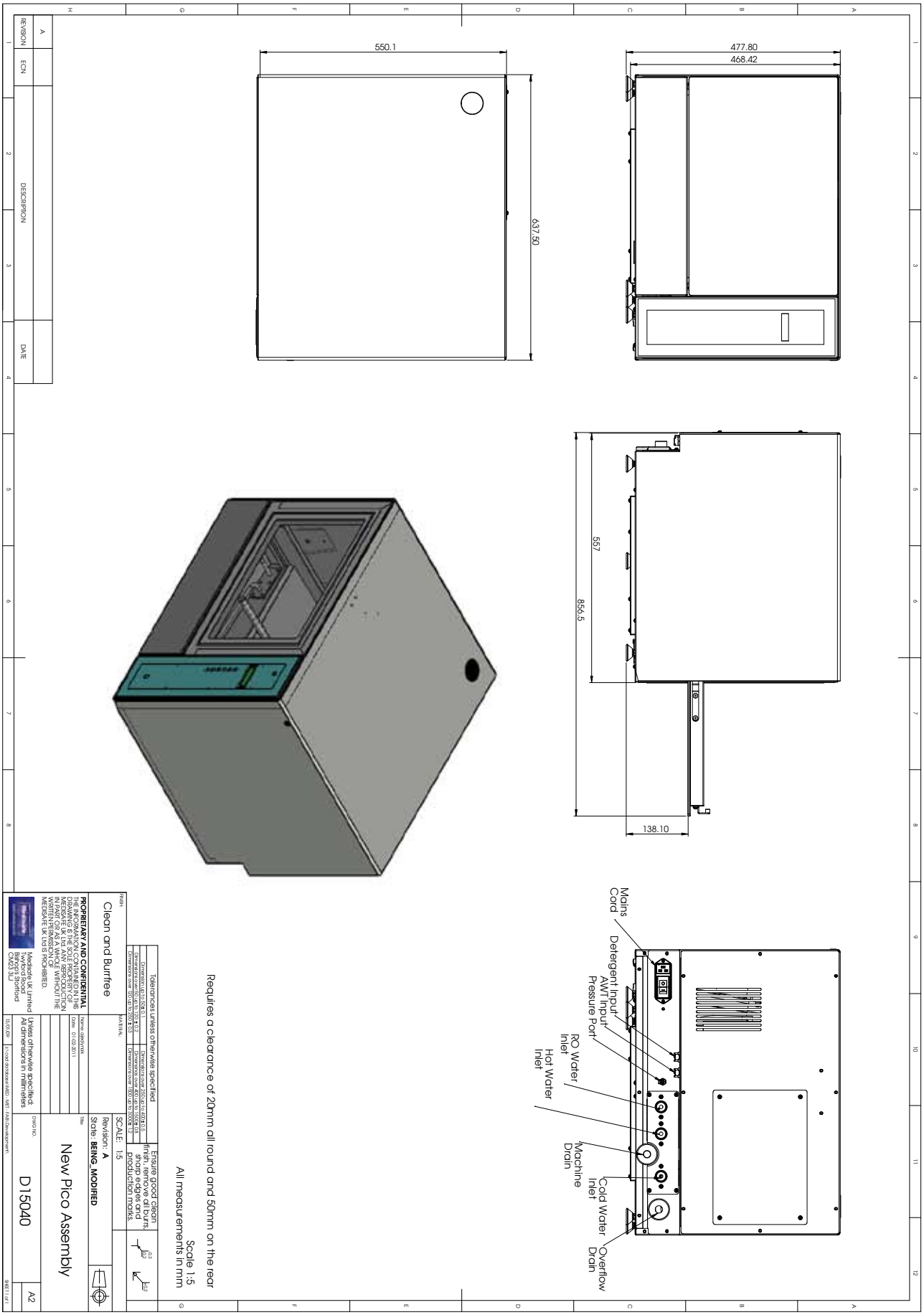
INSTALLATION	
■ The product must be unpacked and sited on a stable and level work top capable of supporting a maximum weight of 55kgs and should be installed 50mm away from side walls and 75mm from back wall for ventilation purposes. ■ There should be enough free space provided near the machine for safe and efficient maintenance in future.	
WATER SUPPLY	
Hardness ($CaCO^3$):	< 55ppm[1] as per HTM0105, refer page 65 clause 17.10
Pressure:	1 - 3 Bar [2]
Temperature:	15 – 25°C (Cold), 50 – 60°C (Hot)
Connections:	1 x shut off valve with ¾" BSP male thread (Cold)
	1 x shut off valve with ¾" BSP male thread (Hot)
Position of connections:	Within 1 meter of proposed installation
ELECTRICAL SUPPLY	
Voltage & Frequency:	230 Vac nominal (+/- 5%) @ 50Hz
Outlets:	2 x 13A, 3 pin outlets with total capacity of 13A
Position of outlets:	Within 1 meter of proposed installation
Method of disconnect:	Remove mains plugs
Note: *In case of washing glass products, i.e.: Mirrors, RO water supply(<20 µS) is recommended*	
DRAINAGE SYSTEM	
Type:	2 x 1½" dia. drains fitted with suitable traps
Position:	Below the drain outlet of the machine
Capacity:	>20 l/minute
PRINTER SHELF	
Dimensions	Suitable provision (230mm wide x 280mm deep) should be made for locating the Thermal Printer. Power supply connection for printer should be situated near the printer shelf.
Position:	Above or to right of the machine and within 1 meter from the machine
CHEMICAL SHELF	
Dimensions	Suitable provision for detergent & AWT (270mm wide x 230mm deep) should be made.
Position:	Detergent & AWT must be kept at machine level

1. If mains water pressure is lower than 1bar, a pressure booster pump must be installed and if water pressure is higher than 3bar than a pressure reducing valve must be installed. Please see part numbers and prices below

Part Number	Description	Price excluding VAT
MED8931	Pressure booster pump Assembly	£290.00
VALVE025	Pressure reducing Valve	£150.00

2. Above this value AWT must be used during the cycle. The amount of AWT depends on the hardness of the water, please contact Medisafe UK Ltd service department (Tel: 01279858400).
3. In case Printer and Medi-Loggers are connected to same machine, an extra 13A mains power outlet must be installed
4. There are two drain hose connected to the machine for overflow and machine's drain.

Note: Failure to install your PICO evo following the above guidelines could invalidate your warranty.


550.1
637.50
477.80
468.42
557
856.5
138.10
Mains Cord
Detergent Input
AWI Input
Pressure Port
RO Water Inlet
Hot Water Inlet
Machine Drain
Cold Water Inlet
Overflow Drain
Requires a clearance of 20mm all round and 50mm on the rear
Scale 1:5
All measurements in mm
REVISION
ECN
DESCRIPTION
DATE
A
Clean and Burrfree
Revision: A
Scale: BEING_MODIFIED
SCALE: 1:5
New Pico Assembly
D15040
A2
PROPRIETARY AND CONFIDENTIAL
Medcraft UK Limited
Bishop's Stortford
CM23 3JJ

Important Note:

Medisafe (UK) Ltd. strongly advise that this product be installed and commissioned by Medisafe or by a suitably qualified person before use.

Connecting the Washer Disinfector

1. Place the product on a sturdy, level surface within 1 meter of a mains supply (two supplies if the optional printer or Medi-Logger has been specified), suitable drain, and suitable hot and cold water supply as detailed with in the Installation Requirements.

Mains isolation is achieved by removing the plug so ensure that the outlet is easily accessible.

Important Note:

The PICO evo washer disinfector must earthed.

2. Connect the mains plug into the switched outlet and switch on. This product must be connected to a suitable mains power supply to enable the loading door to be released.
3. Open door and remove any protective packaging and loose items from inside the wash chamber.
4. Close door, switch mains off at power outlet, and remove mains plug.
5. Identify two grey plastic convoluted drain hoses attached at the back of the unit. Connect these hoses to suitable mains drain sited below the level of the drain outlet on the unit.

6. Identify the blue and Red water supply hose supplied with the unit. Connect both of them with the respective cold and hot water inlet given at the lower rear of the unit. Connect the other end to a suitable water supply.

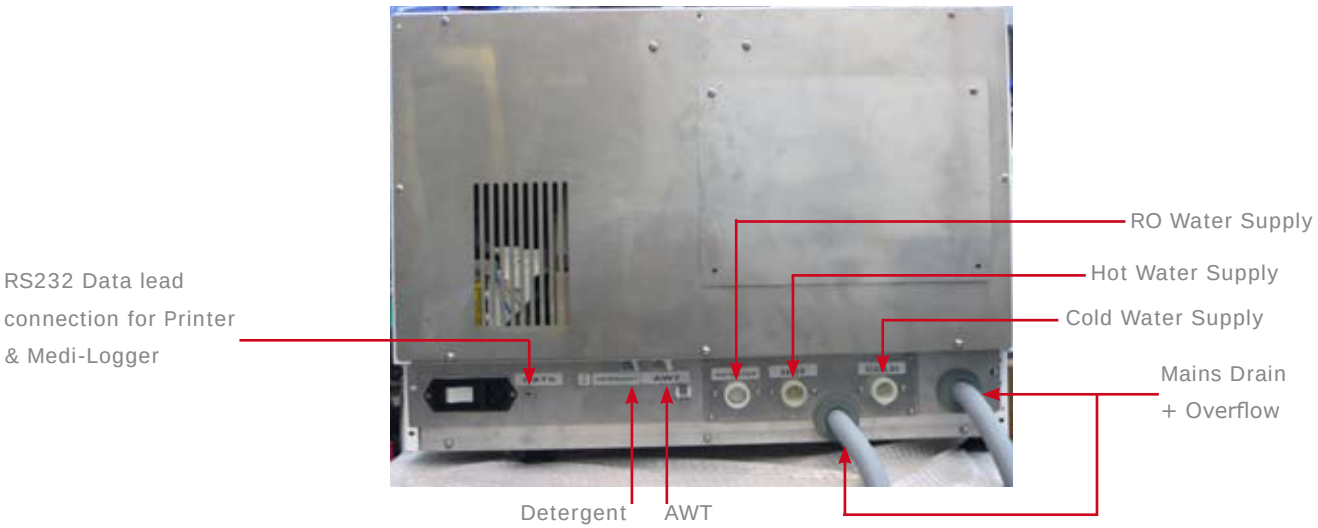
Important Note:

Ensure that the black plastic washer fitted to the supply hose end is in place before tightening.

Chemical Safety Note:

Before handling of any chemical please read Chemical Safety Information on page 7.

7. There are two quick release ports provided on rear of chassis and are labelled as “Detergent” and “AWT”. Remove cap from 3E-Zyme detergent bottle and place filter on end of pick-up tube into bottle.



8. Fit connector on other end of pick-up tube to quick release port labelled as “Detergent”.
9. Similarly, remove the cap from AWT bottle and place inlet tube with cap on the bottle.
10. Fit connector on other end of pick up tube to quick release port labelled as “AWT”.
11. Plug the mains plug into a suitable switched outlet and switch on.
12. After installing new detergent & AWT it is important to purge detergent and AWT before using the machine. The guidelines to purge detergent and AWT are given on page 34 and 35 respectively.
13. Turn ON the water supply and check for any leaks.
14. Your PICO evo. Washer Disinfector is now ready to use.

Connecting the Printer (If supplied)

1. Identify the RS232 Data Lead supplied with the PICO evo.. Connect the 3.5mm jack plug to the data port on the lower rear panel of the PICO evo. unit.
2. Connect the multi-pin plug on the other end of the RS232 Data Lead to the connector on the rear of the printer .

3. Identify the plug-top power supply packed with the printer . Connect to socket on rear of printer and plug into a suitable mains supply outlet and switch ON.
4. Turn the Printer ON using the switch located on the left hand side.

Connecting to a Data Logging PC.

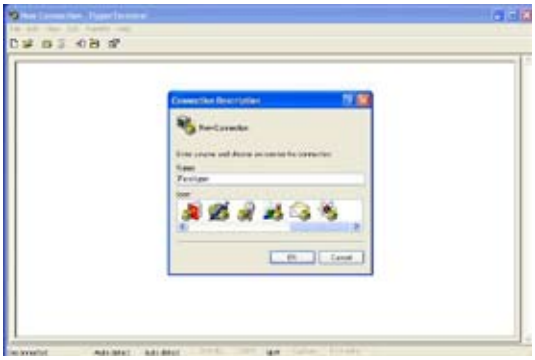
The PICO evo transmits data of a wash cycle from the serial port at a speed 2400 bits per second (8 data bits, no parity, 1 start bit, 1 stop bit, no handshaking). As an alternative to a printer, this data may be sent to a logging device or to a computer via the serial port COM1 or COM2 and Microsoft's Hyper Terminal programme.

1. Identify the RS232 Data Lead (see image on left) supplied with the unit. Connect the 3.5mm jack plug to the data port on the lower rear panel of the unit.

2. Connect the multi-pin plug on the other end of the RS232 Data Lead to the COM1 or COM2 port on the PC.

3. Locate the Hyper Terminal program in (Programs\Accessories\Communications\HyperTerminal) and click Hyper Terminal.

4. Enter name, e.g. 'PicoHyper', and select an



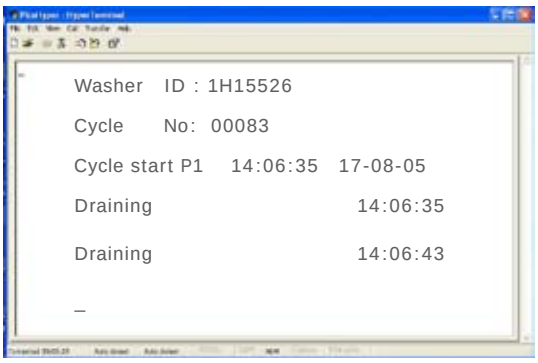
   icon from those provided. Click 'Ok'.
5. By default, COM1 is selected as the communications port. Click 'Ok'.

6. The name of the Hyper Terminal bar has changed to 'PicoHyper – Hyper Terminal' and you now have your own Hyper Terminal.

7. From the File menu, select Properties >> Settings >> Terminal Keys:

   Ctrl+H is selected
   Emulation is set to 'Auto Detect'
   Terminal ID is set to ANSI
   Buffer is set to 500
   Tick 'append line feeds to receiving ends'
   Tick 'wrap lines that exceed terminal width'
   Click 'Ok' to accept port initialization

8. From the Transfer menu, select Capture Text. The incoming data needs to be stored in a file so enter the name of a directory and filename, e.g., 'C:\PicoHyper\DataLog.txt' or browse around and find a suitable folder before adding the name of the file you want to save the data in. Click 'Start'.
9. The PicoHyper Hyper Terminal is now ready and, if linked to a PICO evo, will be receiving data.
10. When the PicoHyper is closed, all received data will be saved in the DataLog file. Next time you use the Hyper Terminal, use the File menu and select Open. When you choose to open your Hyper Terminal (i.e., click 'PicoHyper'), go to the Capture Text menu and either enter a new file name for the data or retain the existing one, in which case new data will be appended to it. When you have made your choice, click 'Start' to begin receiving data when the PICO evo is connected.



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Section 3: Operation

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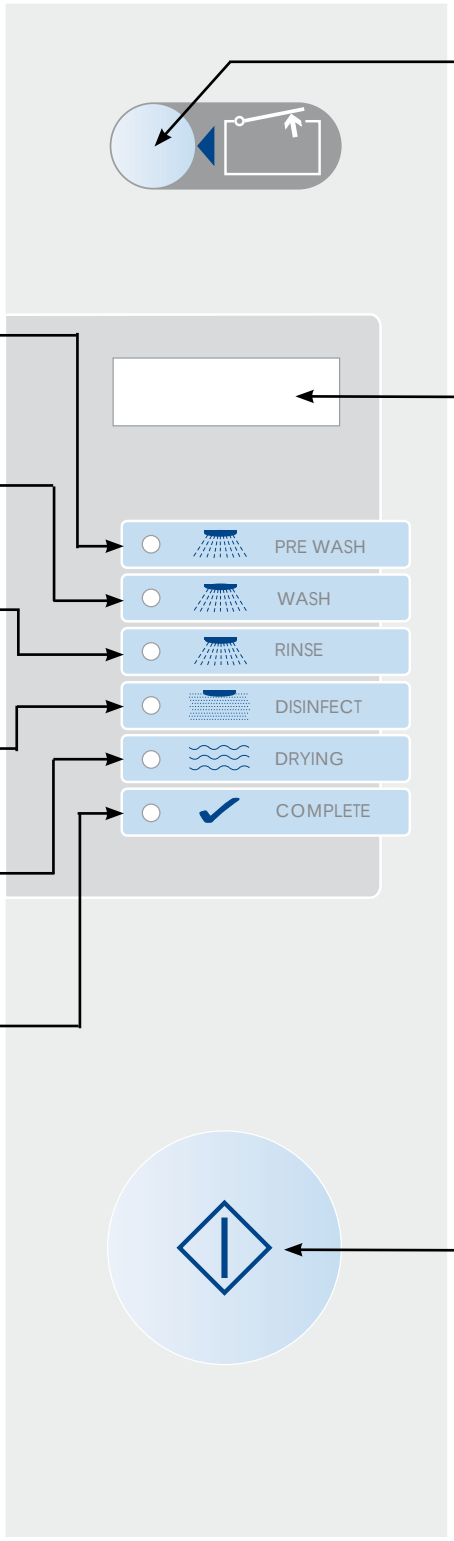
Important Note:
If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired



DOOR RELEASE
Press to open door. Press in 'paused' mode to abort cycle. Also used to amend settings during default changes.

LCD DISPLAY
Indicates wash/ disinfect information at every stage of cycle and displays any error messages

PRE-WASH
Cold water pre-wash stage of cycle is in progress

WASH
Main wash stage is in progress

RINSE
Load is being rinsed prior to disinfection stage

DISINFECT
Disinfection stage is in progress

DRYING
Drying stage is in progress

COMPLETE
Cycle is complete and load may be removed once cooled

START BUTTON
Press once to start or pause the wash cycle.
Also used to change default settings.

IMPORTANT
The door cannot be released unless the product is connected to a mains power supply. To manually open door, please refer to Section 3-10 on page 30.

Changing Language

The LCD display on the front panel of the product can be programmed to display text in one of four different languages. Once selected, a language becomes the default setting until the procedure is repeated and an alternative selection is made. The languages are scrolled in the following order:

1. *French*
2. *German*
3. *Spanish*
4. *English*
5. *Japanese*

Procedure

Important Note:
The time allowed to make an entry is relatively short so prompt input is required once the sequence has been commenced.

1. Disconnect product from mains supply, wait a few seconds, and then reconnect.
2. Observe the messages shown on the LCD display whilst following the procedure.
3. Press and hold the START button until 'select language' prompt is displayed.
4. Press and hold the START button until required language is displayed.
5. Press the DOOR RELEASE button once only.
6. The selected language is now stored.

Important Note:
If product is not fitted with a removable mains plug then consult a qualified person before attempting to disconnect power supply.

Procedure

1. Ensure that the following screen is displayed before attempting to adjust programme, date, or time settings.

   Load Instruments
   Check Detergent

2. Press and hold DOOR RELEASE button for at least 2 seconds.
   The following screen will now be displayed. Holding the START button will cause the display to scroll through programmes 1 to 4. (See Changing Programmes in Section 3-4 for details on setting the correct programme).

   Set Clock & Prog
   PROG 1

3. After a few seconds the following screen will be displayed with a prompt flashing before the HOUR segment of the display. Press and hold the START button until the correct HOUR is displayed.

   Set Clock & Prog
   TIME _00:00:40

4. Momentarily press the START button.

5. The following screen will now be displayed with a prompt flashing between the HOUR and MINUTES segments of the display. Press and hold the START button until the correct MINUTES are displayed.

   Set Clock & Prog
   TIME 14_00:40

6. Momentarily press the START button.

7. The following screen will now be displayed with a prompt flashing after the SECONDS segments of the display. Press and hold the START button until the correct SECONDS are displayed.

   Set Clock & Prog
   TIME 14:30:40_

8. Momentarily press START button.

9. The following screen will now be displayed with a prompt flashing before the DAY segment of the display. Press and hold the START button until the correct DAY is displayed.

   Set Clock & Prog
   DATE _01:01:00

10. Momentarily press the START button.

11. The following screen will now be displayed with a prompt flashing between the DAY and MONTH segments of the display. Press and hold the START button until the correct MONTH is displayed.

    Set Clock & Prog
    DATE 01_08:00

12. Momentarily press the START button.

13. The following screen will now be displayed with a prompt flashing between the MONTH and YEAR segments of the display. Press and hold the START button until the correct YEAR is displayed.

    Set Clock & Prog
    DATE 01:08_00

14. Momentarily press the DOOR RELEASE button once to save changes and exit menu or press START to return to step 2 (above).

Washing is achieved using unique, specially formulated and clinically validated detergents which are introduced during the operating cycle to clean away fats, proteins, starches, body fluid residues, etc. Two types of detergent may be used, a liquid enzymic detergent (3E~Zyme) or a liquid alkaline detergent. Both types of detergent are drawn into the wash chamber, via a flexible hose, from a container located adjacent to the unit.

Important Note:

The PICO evo. MUST be reprogrammed each time the detergent type is changed.

The following tables indicate the target parameters for each of the programmes which must be met to ensure compliance with International Standards. The accuracy of these parameters may be monitored by observing a print-out from the Thermal Printer (if supplied) or by viewing the Front Panel LCD as a cycle progresses. This should be done every day as part of your ACT (Automatic Control Test) - See Routine Checks in Section 3-7 for more information.

Changing Programmes

To change programmes follow this procedure:

1. Ensure that the following screen is displayed and then open loading door by pressing the DOOR RELEASE button.

Load Instruments
Press START

2. Once door is open, press and hold DOOR RELEASE button.
3. Use the START button to scroll through the time and date settings until the following programme prompt is displayed.

Set Clock & Prog
PROG 1

4. Holding down the START button will cause display to scroll through programmes 1 to 4. Release when the required programme is displayed.

5. Press DOOR RELEASE button once to save changes and exit menu.

Important Note:

Once selected, a programme becomes the default until the procedure is repeated and an alternative selection is made.

	P1 (Intensive)	*P1 (Express)*	P2 (Medi-PH-Safe)	P3 (3E~Zyme)	P4 (Medi-PH-Safe)
No. of Pre-Wash	002	*000*	001	001	001
Pre-Wash duration	3 mins	*0mins*	3 mins	3 mins	3 mins
Main Wash duration	10 mins	*5 mins*	5 mins	5 mins	5 mins
Main Wash temperature	52°C	*42°C*	53°C	43-45°C	53°C
No. of Rinses	003	*002*	002	002	002
Rinse duration	1min	*1 mins*	1 mins	1mins	1 mins
Disinfection duration	10 mins	*1 mins*	10 mins	10 mins	10 mins
Disinfection temperature	82°C	*90°C*	80 - 85°C	80 - 85°C	80 - 85°C
Drying	25 mins	*10 mins*	20 mins	20 mins	20 mins
Drying temperature	82°C	*70 - 82°C*	82°C	82°C	82°C

Important Information on Loading Instruments

The capacity of maximum load on PICO evo. Benchtop Washer Disinfector is 86 Instruments with 6 dental hand pieces.

When loading instruments be sure to observe the following precautions:

Do not drop items into the chamber.

Do not Instruments should be loaded in such a way so that spray arms movement is not distracted.

Do not over load the basket.

Always use Dental Handpieces that are compliant with Washer Disinfector cleaning and clearly marked with the following symbol.

Important Note:
If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired

Loading the Basket

Fit dental hand piece on the manifold (if available).

Note that whenever dental hand-pieces are placed into manifold, it is important that any spare dental hand piece holder on manifold are blanked off with the caps supplied with the machine. This will ensure that an effective irrigation flow is achieved through each dental hand piece device and not by-passed through the spare Luer connectors.

Place load into large basket and slide into the wash chamber, ensuring that the basket locates correctly in docking port in rear of wash chamber.

Note that water is sprayed up from the bottom of the chamber so large items, such as trays and bowls, should NOT be placed flat on the bottom of the large basket as this will obstruct the water spray.

Important Note:
Do not overload the large basket so that water spray is obstructed.

Commencing a Cycle

1. Apply power to the product and press the DOOR RELEASE button to open the door.

Warning:
Ensure that the filter on the pick-up tube is immersed in detergent before commencing a wash cycle. Failure to do so will result in an aborted cycle if sufficient detergent is not available. To replenish an empty detergent container, remove filter on pick-up tube from bottle and place into full container.

2. Close the door.
3. Observe the messages shown on the LCD display and follow this procedure:
4. If this message is displayed then refer to “AWT Replenishment”.

Load Descaler
Press START

5. Press START button once.

   If AWT Fluid has already been added then continue. If not, then refer to AWT Fluid Replenishment in Section 3-8.
   (The descaler messages will only be shown at very first power-up or when AWT Fluid is low.)

IF Descaler IN
Press START

6. Press START button once.
7. When the following message is displayed, load instruments. Press START button once.

Load Instruments
press START

9. When the following message is displayed, ensure that all instruments are correctly loaded and press START button once.

IF All Loaded
Press START

The Wash and Disinfection cycle will now commence and proceed automatically as detailed in “Operating Process”. When the cycle is complete the door will automatically unlock and the following message will be displayed:

Cycle complete Press START

The following message sequence will now be displayed and repeated:

WARNING Chamber Hot	Unload Press START

Important Notes:

The START button must be pressed after the cycle has finished and when the door is still open. This is to acknowledge that the instruments have been unloaded.

If the door is closed before pressing the START button, further cycles will be prevented.

If the door is closed before the START button is depressed, then re-open door and press START.

WARNING!

Risk of burning. At the end of cycle, internal surfaces of the machine may be hot up to 85°C. All internal and external high temperature surfaces including instrument basket and inner door must be allowed to cool down before unloading the load.

Pausing a Wash Cycle

To pause operation at any time during the wash and disinfect cycle, press & hold the START button.

To resume operation after pausing, press the START button once.

Aborting a Wash Cycle

To abort a wash and disinfect cycle, press the START button once and then the DOOR RELEASE button.

The program will automatically go to drain, the cycle will be aborted, and the following message will be displayed.

PROGRAM ABORTED

WARNING!

Risk of burning. If program is aborted at any stage of the cycle, the internal surfaces of the machine may be hot up to 91°C. All internal and external high temperature surfaces including instrument basket and inner door must be allowed to cool down before unloading the load.

To ensure that your PICO evo continues to operate within the design parameters, and to ensure continued compliance with the guidelines identified as acceptable by international decontamination standards, it is recommended that the following checks are performed on a regular basis. Consulting the Fault Finding guide may prove useful when conducting the checks.

Important:
Please note that completion of these checks is not a substitute for regular servicing and maintenance by a suitably qualified engineer.

Daily Checks - What to do and ▶ How to do it:

1	Verify accuracy of electronic control systems	▶	Select a recent printout (if a printer is connected) and compare parameters with the first printout generated after installation.
2	Check cleanliness of all external surfaces	▶	Clean with a weak mixture of detergent and water
3	Check that the inside of the wash chamber is clean and free from any deposits	▶	Clean with a weak mixture of detergent and water
4	Check that the perforated sump cover at the bottom of wash chamber is not clogged	▶	Cleaning with AWT Fluid and then flush through with fresh water
5	Check that holes in the rotating spray bar are not blocked and it is free to rotate without restriction	▶	Remove spray arm by unscrewing clockwise, clean with AWT Fluid, and then flush through with fresh water
6	(If dental handpiece manifold fitted:) Check that the dental handpiece manifold .	▶	Ensure that manifold seal is in good condition.
7	Check door operation	▶	Ensure that loading door is free to open and close without restriction
8	Check that rubber seal around door opening is undamaged free from any deposits	▶	Examine rubber seal around door for signs of deterioration or damage - clean with a meak mixture of detergent and water

Weekly Checks - What to do and ▶ How to do it:

1	Perform Daily Checks	▶	See above
2	Residual Protein test	▶	Perform residual protein test using Pro-TEST Quick or equivalent
3	Check dental handpiece manifold filter	▶	See section 3-12 on how to open the manifold to check and replace the filter.

Monthly Checks - What to do and ► How to do it:

1	Perform Weekly Checks	►	See page 32
2	Check service hose connections	►	Check that all hoses are secure with no evidence of leaking
3	Check that mains power cord is undamaged	►	Examine mains power cord for signs of damage and check that mains plug or electrical connector is properly connected
4	Check basket connections	►	Check that the docking port components located in the wash chamber and on the Large Basket are undamaged and that the basket engages without restriction
5	Check gasket between door and basket	►	Check that gasket on front edge of basket is in place
6	Cleaning Efficacy Test	►	Perform test by using standard PCD kit (Process Challenge Device) or equivalent

WARNING:

Before handling of any chemical please read Chemical Safety Information on page 8.

One AWT bottle contains sufficient anti-scaling fluid for up to 70 wash and disinfect cycles (dependent upon water hardness and default settings used). On completion of 50 cycles, the LCD DISPLAY will indicate that more fluid is required and the unit will not proceed with a new wash and disinfect cycle until you confirm that it has been added.

After replacing AWT bottle, it is important to purge AWT through the empty inlet hose to take all blocked air. To purge AWT manually follow steps below.

1. Ensure that the following screen is displayed before attempting to go into test mode.

Load Instruments
Check Detergent

2. Press DOOR RELEASE button once to open the door. Once door is open, press DOOR RELEASE button again for at least 5 seconds. The following screen will now be displayed.

Set Clock & Prog
PROG 1

3. Press START button once and following message will be displayed,

Set Clock & Prog
TIME _00:00:40

Set Clock & Prog
TIME 00_00:40

4. Press START button three times and cursor will move from hours to minutes and then display will show “DATE” option as below.

Set Clock & Prog
DATE _01:01:00

5. On pressing START button three times, the cursor will move from date to month and at the end it will be blinking under the year.
6. Press START again and “Prime AWT Pump” will be shown as below

Prime AWT Pump
AWT = OFF

7. At this point press and hold START button. This will switch ON AWT pump and AWT will be purged through the hose for 4 to 5 seconds and will stop automatically. Remove figure from START button.
8. When AWT pump is ON, it shows AWT=ON on screen and when it stops automatically it shows AWT=OFF.
9. Press START again to prime AWT again and repeat this procedure until AWT can been seen coming through the water inlet diffuser. The water inlet diffuser location shown in the picture below.
10. Once AWT is purged, press DOOR RELEASE button twice to go back to standby mode as following

Load Instruments
Check Detergent

WARNING:

Before handling of any chemical please read Chemical Safety Information on page 8.

After replacing the new chemical container, it is important to purge chemical through the empty chemical hose to take out all blocked air. Please follow chemical safety information on page 35. To purge chemical through the test mode follow the steps below

1. Following two messages can be shown on LCD display before start of procedure.

Load Instruments Press START	Check Detergent

If display shows “Load Instruments”, then go to step no.4

If display shows “Check Detergent”, then go to step no.2

2. To clear this, user need to switch off the machine from the mains switch on the wall and switch back ON. This will then display “Program Aborted, Power Failure”

3. Press DOOR RELEASE button once to open the door. Once door is open, press DOOR RELEASE button again for at least 5 seconds. The following screen will now be displayed.

Set Clock & Prog PROG 1

4. Press START button once and following message will be displayed,

Set Clock & Prog TIME _00:00:40	Set Clock & Prog TIME 00_00:40

5. Press START button three times and cursor will move from hours to minutes and then display will show “DATE” option as below.

Set Clock & Prog DATE _01:01:00

6. On pressing START button three times, the cursor will move from date to month and at the end it will be blinking under the year.
7. Press START again and “Prime AWT Pump” will be shown as below

Prime AWT Pump AWT = OFF

8. Press START and “Prime Det. Pump” will be shown as below.

Prime Det. Pump Det. = OFF 00

9. To purge the detergent, press START to switch ON detergent pump and it will count the detergent quantity from 00 to 10. This is shown on right hand side of the display. When detergent pump is ON, display shows “Det. = ON” and after counting up to 10 it stops automatically and shows Det.=OFF.

10. Press START again to prime detergent and repeat this procedure until detergent can be seen coming through the water inlet diffuser. The water inlet diffuser location inside the chamber is identified in the picture on previous page.

11. Once detergent is purged, press DOOR RELEASE button twice to go back to standby mode as below

Load Instruments Check Detergent

Procedure

If the product fails to operate due to a fault with the electricity supply then the loading door will remain locked until power is restored. In the unlikely event that an internal fault causes a failure, the loading door can be released manually using the Door Release Probe supplied with the product. If the outer cover needs to be removed by a qualified person, then access to the securing screws can only be gained if the door is in the open position.

IMPORTANT

Opening the door using this procedure will enable access to a partially cleaned load and it is therefore essential that the cycle is recommenced as soon as possible.

1. Remove mains connector from supply socket or isolate power if connected directly to a fused spur.
2. Unscrew (anti-clockwise) threaded plug towards the top, right-hand side of the Outer Cover (fig 1)
3. Insert Door Release Probe into exposed hole and push firmly (fig 2)
4. The loading door will now be released
5. Replace threaded plug.

Fig 1. Unscrew threaded plug

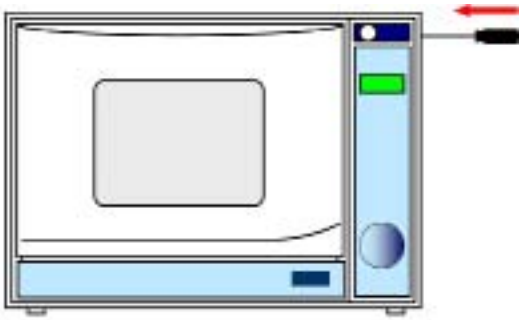


Fig 2. Insert Door Release Probe and push firmly in direction of arrow

PICO evo®

Section 4: Technical

Rev.C

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Overview

The PICO evo Washer Disinfector uses a microprocessor controlled operating sequence to alternately spray accurately measured amounts of temperature-controlled water from a rotating spray bar onto items loaded into purposely designed baskets and containers. water is also pumped through dental handpieces connected to a manifold. A specially formulated detergent is added to the water to clean away fat, protein, starch, body fluid residue, etc. A small quantity of scale inhibitor prevents the formation of deposits on both the items being cleaned and the component parts of the washer itself.

The filling starts with Cold water entering the wash chamber from the mains water supply via an electronically controlled valve until a level sensor interrupts and cuts off the incoming water. If a failure should occur in the level sensor then a second, independent sensor will react to cut off the water supply and prevent overflowing.

Once the wash chamber is filled, the pre-wash stage begins to remove larger deposits from the load. A pump circulates water from a sump and up through a rotating spray bar in the base of the wash chamber. To perform flushing and irrigation, the water is cycled alternately between the rotating spray arm and a docking port which connects, via a manifold to the basket containing hollow instruments. The pressure of the water passing through this spray bar causes it to rotate, thereby assisting even distribution and a constant flow of water over and around the items to be cleaned and disinfected. The pressure of water passing through the hollow instruments assists in removing deposits and residue.

Once the pre-wash stage finished, Hot water will be used from hot water supply for the main wash, which includes washing, Rinsing and Disinfection procedures.

In auto-dosing system, a small pump (controlled by the microprocessor) introduces detergent from an external container at the appropriate stage(s) of a wash cycle. A flow sensor in-line with the pump reports to the microprocessor. Failure to admit the correct amount of detergent will result in an aborted cycle. A filter fitted to the pick-up tube is dropped into the detergent container and the other end is connected via a ‘quick release’ connector mounted on the rear panel.

The sump, situated in the base of the wash chamber, contains an element which is used to heat the water to either 43°C or 53°C (depending on the detergent used) before a further wash commences. Once complete, the water is then drained and replaced with fresh Hot water to perform the first of two rinse stages. Immediately prior to the second rinse, a small quantity of scale-inhibitor (AWT Fluid) is automatically injected into the rinse water.

Water is then heated to the correct temperature ready to perform a disinfection cycle. The Hot water is intermittently circulated within the tank and through the hollow instruments during the heating period in order to aid thermal efficiency and to reduce the overall cycle time.

Once the correct temperature is reached the disinfection cycle begins. The microprocessor then accurately controls the temperature of the water via two independent temperature sensors. This ensures that the correct temperature is maintained for the duration of the disinfection stage.

Finally, the circulation pump is driven in reverse to drain the wash chamber for the final time. Once the wash chamber is emptied the LCD Display indicates that the cycle has been successfully completed. If for any reason an error was recorded during the cycle then the washer will advise this by displaying the message “cycle failed” at this time. In order to prevent unclean/non-disinfected items from being removed prematurely, the loading door will remain locked until the failed cycle is acknowledged. Such an interruption to the cycle will be notified with a “PROGRAM ABORTED” message.

Each cycle has a unique, sequential number and contains information regarding date, time, temperature, and duration of each stage of the cycle to afford total trace-ability. An RS232 Data Port at the rear of the washer allows the connection of an external printer to display the data in printed form, or to a data logging device or computer.

The following table will enable a non-technical user to diagnose basic problems and affect a cure that will enable normal operation to be resumed as soon as possible.

If the problem persists after performing these checks it will be necessary to contact your supplier.

Symptom	Possible Cure
Loading door will not open	► Check power cord is properly connected ► Check mains supply is switched on
No read-out on LCD Display and no LED illumination on front panel	► Check power cord is properly connected ► Check mains supply is switched on
Unit fails to take in cold water but LCD Display indicates “Filling … ”	► Check that Hot/cold water supply is connected ► Check that hot/cold water supply is switched on ► Check that Hot/cold water hose is not kinked
Unit fills too slowly with cold water	► Check that filter in Hot/cold water inlet valve is not blocked(remove cold water hose to access filter)
LCD Display on unit indicates “Program aborted” during cycle	► Check that loading door has not been opened during cycle
LCD Display on unit indicates “Power failure, cycle aborted … “	► Check that mains supply to unit has not been temporarily disconnected and then reinstated within a timescale which has compromised the cycle
Printer (if applicable) fails to operate	► Check that printer is connected to mains supply ► Check that mains supply is switched on ► Check that printer is switched on ► Check that data lead is securely plugged into sockets on Washer Disinfector and printer ► Check that printer has not run out of paper
Inside of wash chamber is coated with white scale	► Check to see if AWT Fluid needs replenishing (see “AWT Fluid Replenishment”)
Cycle is aborted due to low detergent level (Auto Dosing variants only)	► Check to see if detergent needs replenishing (see “3E-Zyme Replenishment”)
Perforated sump cover in bottom of wash chamber is blocked	► Remove cover, clean by immersing in AWT Fluid, and then flush out

General

Medisafe PICO evo Range (230V/50Hz operation) Product Code: MED1360

Description: Washer Disinfector, Class IIa

Type: Cabinet (single chamber) machine (type 1)

Purpose: To clean and disinfect surgical instruments and associated products

Operating process: Thermal Disinfection

Applied standards:

HTM 2030 (1997)	BS EN 62366 : 2008
HTM 2030 (1997)	EN 61326 : 2006
HTM 01-05 (2009)	ISO13485 : 2003
EN ISO 15883-1: 2009	ISO 14971 : 2009
EN ISO 15883-2 : 2009	CEI IEC 878
EN 61010-2-040 : 2005	BS5304 / PD5304 : 2005
EN 60601-1-2 : 2007	Low Voltage Directive 2006/95/EC
BS EN 60601-1-6 : 2010	Physical Agents Directive 89/391/EEC
EMC Directive 89/336/EEC	Supply of Work Equipment Regulations (SOWER)
Management of Health & Safety at Work - Regulations (MHSWR)	Water Supply (Water Fittings) Regulations 1998

Environmental conditions:

Indoor use;
Altitude up to 2000m;
Temperature 5°C to 40°C;
Maximum relative humidity 80% for temperatures up to 31°C decreasing linearly to 50% relative humidity at 40°C;
Mains supply voltage fluctuations up to ±10% of the nominal voltage;
Transient overvoltages typically present on the mains supply (Overvoltage Category II).
Pollution Degree 2

Wash Cycle Parameters

Wash temperature: Nominal 42°C. using 3E-Zyme solution

Disinfection conditions: Moist heat @ 80°C. to 85°C.

Disinfection period band: 80 - 85°C. for minimum period of 10 minutes

Holding time: 10 minutes @ Disinfection Conditions

Equilibration time: Approximately 3 minutes

Plateau period: Approximately 5 minutes

Min temp during cycle: Determined by temperature of water supply

Max temp during cycle: 85°C.

Accuracy of temp measurement: < 2% @ 85°C.

Volume of dispensed chemicals:

AWT Fluid: Depends on quality of water

3E~Zyme: Depends on type of cycle

Required Services

Electricity Supply

Supply type required: Single phase, 230V nominal (+/- 10%) @ 50Hz

Power consumption: 2.4KVA max.

Termination (Pico): 1 x mains connection plug on 1.83m (6 feet) cable

Termination (Printer): 1 x mains connection plug on 1.83m (6 feet) cable

Method of disconnect: Remove mains plug

Water Supply Connection on product: 1 x ¾" BSP Male Union (cold)

1 x ¾" BSP Male Union (Hot)

Service connection required: Shut off valve with ¾" BSP male thread positioned within 1m of product

Acceptable pressure range: 1–3 bar, 15 – 45 psi (2–3 bar, 30 – 45 psi

Effect of reduced pressure: Increased filling time leading to extended total cycle time

Acceptable flow range: Not less than 2 litres/min

Effect of reduced flow: Increased filling time leading to extended total cycle time

Volume used per stage: 5.5 litres maximum

Acceptable temp range: 15 - 25°C (cold)

50 - 60°C (Hot)

Hardness: Caco3, Not more than 55ppm as per HTM0105 refer page 65 clause 17.10. (Above this value AWT will must be used during the cycle.

Drain

Connection on product: 2 x 18mm outside dia. unthreaded hose tail

Service connection required:

2 x 1½" dia. drain fitted with suitable trap located below level of work surface with drainage capacity in excess of 20 litres/min

Maximum flow to drain: 4 litres/min

Maximum temperature of effluent: 85°C

Ventilation: Maximum temperature of load, 85°C

Chemicals

Size and Nature of Containers:

AWT Fluid: 0.5 litre plastic bottle with spout

3E-Zyme: 5L bottle with screw cap

Storage Instructions:

Refer to Chemical Data Sheet provided with chemical.

Safe Handling Instructions:

Refer to Chemical Data Sheet provided with chemical.

Quantity Used per Cycle:

AWT Fluid: Depends on the quality of water

3E-Zyme: Depends on type of cycle

Weights & Dimensions

Dry weight: 55kg (empty)

Operational Weight: 65kg (with fluids)

Shipping Weight: 75kg

Internal Dimensions:

Front to Back: 465mm (18.3")

Width: 435mm (17.12")

Height: 300mm (11.81")

Wash Chamber Size: 60.68 litres (16.03 US Gal)

External Dimensions:

Front to Back: 557mm (21.92")

856mm (33.70") with door open

Width: 637mm (25.07")

Height: 477mm (18.77")

Carton Dimensions: 640 mm (w)

540 mm (d)

480 mm (h)

Product Warranty

To ensure continued efficiency and long operational life, your new Washer Disinfector is covered by a 12 month or 1200 cycle (whichever occurs first) warranty which is arranged and administered by Medisafe (UK) Ltd. Details of the warranty are explained in this section.

Subject to the following terms and conditions, Medisafe (UK) Ltd. warrants that any item of THE BASIC WARRANTY ITEMS of the unit (hereinafter called “new Washer Disinfector”) manufactured by Medisafe (UK) Ltd. shall be free from any defects in material and workmanship under normal use.

Any item of THE BASIC WARRANTY ITEMS covered by the limited warranty will be repaired or replaced free of charge by Medisafe (UK) Ltd. or any distributor authorised by Medisafe (UK) Ltd. to act as their agent (hereinafter called “authorised Medisafe dealer or distributor”).

The factory set parameters are designed to provide the most efficient cleaning with disinfection using the manufacturers recommended detergents while giving the maximum reliability from the PICO evo..

Any unauthorized changes to the wash parameters may affect the reliability and cleaning efficiency of the PICO evo., as such MEDISAFE reserve the right not to cover the warranty on PICO evo.’s that have been modified outside the factory set parameters.

The Basic Warranty Items

THE BASIC WARRANTY ITEMS are any items (except THE SPECIFIC EXCLUDED ITEMS) of this new Washer Disinfector which are warranted by an authorised Medisafe dealer or distributor within 12 months or 1200 cycles (whichever occurs first) of the WARRANTY START DATE when this new Washer Disinfector is first installed by or for you (the original purchaser) as set forth on the Memorandum of Registration.

THE BASIC WARRANTY ITEMS listed below are warranted within 12 months or 1200 cycles (whichever occurs first) from the WARRANTY START DATE against defects in manufacture.

- Solenoid valves
- Electric motor and pump
- Switches
- Electronic control circuits
- Water heating element

The Specific Excluded Items

THE SPECIFIC EXCLUDED ITEMS are any items of this new Washer Disinfector which are not included in THE BASIC WARRANTY ITEMS and are therefore not subject to the terms and conditions of the PRODUCT WARRANTY.

Expendable items which will deteriorate and require replacement with normal use of the Washer/ Disinfector (for example: rubber door seal strip (lower), rubber door seal (surround), water inlet filter element, various types of gaskets and hoses, lamp bulb (if fitted), and other expendable parts not specifically listed).

Fair wear and tear of any part, normal maintenance service items, and the parts and any material used in connection with the new Washer Disinfector.

Normal deterioration or damage to plated parts, paint coat, and rubber parts caused by daily wear and exposure to atmosphere and environment.

Minor irregularities not affecting quality, performance or function of the new Washer Disinfector parts thereof (e.g. Slight noise or vibration) or which appear only under particular abnormal conditions.

Damage caused by insufficient or improper maintenance (e.g. Negligence of the daily, weekly, and monthly periodic inspections and any servicing requirements as described and specified within this manual).

Damage caused by using a part or lubricants not approved by an authorised Medisafe dealer or distributor or being repaired or replaced by a person who is not an authorised Medisafe dealer or distributor.

Damage caused by accident, abuse, or negligence of the proper handling as set out in this Owner's Handbook, misuse of the new Washer Disinfector, use of the new Washer Disinfector under unusual conditions, and modifications of or to the new Washer Disinfector or any component/parts thereof not recommended or approved by an authorised Medisafe dealer or distributor.

Damage caused by external influences such as chemical spillage, accident, fire, and disasters due to human fault or negligence or Act of God.

Damage to the external casing, wash chamber, load carriers, or any part of the new Washer Disinfector which may come into contact with the load carrier during the process of loading/ unloading the new Washer Disinfector.

All charges incidental to breakdowns, such as loss of use of the new Washer Disinfector, loss of time, inconvenience, telephone, transportation, loss or damage to personal property or loss of revenues, or other matter not specifically included.

Damage caused by incorrect installation of the new Washer Disinfector which could cause operational failure or impairment either immediately after such installation or at any time within the period of this PRODUCT WARRANTY.

Medisafe (UK) Ltd. reserves the right of final decision on all manufacturers' warranty claims.

Nothing herein affects the statutory rights of a consumer.

Service contracts:

Pay As You Go

Calibration and safety test, one visit

Pay As You Go Plus

Calibration and safety test, one visit, plus three emergency call outs.

Bronze

Four visits Calibration and safety test..

Silver

Four visits Calibration and safety test to HTM2030. Plus four emergency call outs,

Medisafe recommend that your PICO evo Washer Disinfector is serviced in accordance with the schedule contained within the Service Manual at intervals of 3 months. This record must be completed by the Engineer conducting the Service and should be made available in the event of a warranty claim or breakdown repair.

Note:
No user serviceable parts inside. Service and repair should be referred to qualified persons only.

3 Month		
Serviced by/ Date		
Cycles since last service		
Next service due	Cycles	Date

6 Month		
Serviced by/ Date		
Cycles since last service		
Next service due	Cycles	Date

9 Month		
Serviced by/ Date		
Cycles since last service		
Next service due	Cycles	Date

12 Month		
Serviced by/ Date		
Cycles since last service		
Next service due	Cycles	Date

15 Month		
Serviced by/ Date		
Cycles since last service		
Next service due	Cycles	Date

18 Month		
Serviced by/ Date		
Cycles since last service		
Next service due	Cycles	Date

21 Month		
Serviced by/ Date		
Cycles since last service		
Next service due	Cycles	Date

24 Month		
Serviced by/ Date		
Cycles since last service		
Next service due	Cycles	Date

27 Month		
Serviced by/ Date		
Cycles since last service		
Next service due	Cycles	Date

30 Month		
Serviced by/ Date		
Cycles since last service		
Next service due	Cycles	Date

33 Month		
Serviced by/ Date		
Cycles since last service		
Next service due	Cycles	Date

36 Month		
Serviced by/ Date		
Cycles since last service		
Next service due	Cycles	Date

All medical washers should be cleaned weekly as part of the routine maintenance for operator's Health and Safety, for the purposes of routine maintenance (PRIOR to the arrival of the engineer) and for transportation.

By decontamination, we refer to the unit being cleaned and disinfected.

Machines returned in an un-cleaned state WILL incur additional charges for cleaning and decontamination.

For the internal or external surfaces a disinfectant cleaner (e.g. Medisafe DISS-ALL - Product code MED8051), or any household kitchen cleaner can be used providing it is marked as a DISINFECTANT CLEANER.

Important safety information:

All safety precautions recommended for the cleaning product used must be adhered to.

In all cases, the wearing of PPE, including gloves and eye-shields are strongly recommended.

Cleaning/decontamination general instructions.

Apply the chosen chemical onto a clean cloth or paper towel and wipe over the surfaces as mentioned below.

Rinse off with tap water on a cloth or paper towel and dry.

For machines with a tank assembly (such as…..) The tank must be filled with clean water containing a 5% solution of household bleach (Sodium Hypochlorite) and then rinsed with clean water.

The internal area that is not immersed including the underside of the lid must also be disinfected.

All units must be drained down thoroughly prior to return.

Note:

By the nature of its operation, this washer disinfector has a tank or chamber area that is immersed in water during all phases of the cleaning/disinfection cycle. Therefore the main tank/chamber should be clean and disinfected at the end of the cycle.

All that is required then is to clean and disinfect the outside surfaces, and around the sides of the door and door seals/hinges, as the normal wash process will not clean them.

If, however, due to the nature of any fault present, the unit cannot be run prior to return, the tank/chamber must be cleaned and decontaminated by hand following the process outlined in the notes above.

DECONTAMINATION CERTIFICATE

ENSURE THAT ITEMS RETURNED TO YOUR SUPPLIER ARE DISINFECTED IN ACCORDANCE WITH THE APPROPRIATE HOSPITAL PROCEDURE FOR EQUIPMENT OF THIS TYPE

A COPY OF THIS FORM MUST BE COMPLETED AND ATTACHED TO THE OUTSIDE OF THE CARTON WHEN RETURNING THE PRODUCT TO YOUR SUPPLIER. WITHOUT THIS FORM BEING VISIBLE THE COURIER AND/OR YOUR SUPPLIER ARE AT LIBERTY TO REFUSE HANDLING OF THE PRODUCT.

I hereby certify that the machine referred to in this document by model number and serial number has been disinfected in accordance with Hospital Procedure

Model No: _____

Serial No: _____

Hospital: _____

Name: _____

Signature: _____ Date: _____

I. Special Instructions / Notes regarding the PICO evo and Electromagnetic compatibility (EMC) testing to EN60601-1-2:2007

1. The PICO evo has been tested regarding it's ability to operate in an environment containing other electrical/electronic equipment (including other medical devices).
2. The purpose of this testing is to ensure that the PICO evo is not likely to adversely affect the normal operation of other such equipment and that other such equipment is not likely to adversely affect the normal operation of the PICO evo..
3. Despite the testing of the PICO evo that has been undertaken, normal operation of the PICO evo can be affected by other electrical/electronic equipment and portable and mobile RF communications equipment.
4. As the PICO evo is medical equipment, special precautions are needed regarding EMC (electromagnetic compatibility).
5. It is important that the PICO evo is configured and installed/put into service, in accordance with the instructions/guidance provided herein and is used only in the configuration as supplied.
6. The PICO evo.'s data cable must be restricted to less than 3m in length and should not be extended by the user. If the PICO evo is used with adapted cables or cables other than those supplied, this may result in increased emissions or decreased immunity of the PICO evo., in relation to EMC performance.
7. It should be noted that the cables provided with the PICO evo should not be used on other equipment. To do so may result in increased emissions or decreased immunity of the other equipment in relation to EMC performance.
8. The PICO evo should not be used adjacent to or stacked with other equipment. If adjacent or stacked use with other equipment is necessary, the PICO evo and the other equipment should be observed/monitored, to verify normal operation in the configuration in which it will be used.

For the purposes of EN60601-1-2, the PICO evo has an essential performance as follows:

1. Functions within the operating cycle should continue to operate as normal, the product should complete it's operating cycle correctly, wash/disinfect water temperature should remain at 93 deg C, +/- 1 deg C).
2. Slight flickering of the product's LCD display is allowable as is clicking of solenoids / valves during transient type tests, providing the LCD display remains legible and the solenoids / valves do not change state.
3. If the product is subject to electrical interference in the form of Fast Burst Transients (IEC/EN 61000-4-4) on the mains supply, the products LCD display is likely to flicker (however the display should remain legible).
4. If the product is subject to electrical interference in the form of Surges (IEC/EN 61000-4-5) on the mains supply, the products solenoids / valves may be heard to "click" briefly, but no change in the actual status of the solenoids / valves should be seen.
5. If the product is subject to dips / interruptions in the AC mains supply voltage (IEC/EN 61000-4-11), the product's LCD display may dim for the duration of the dip/interruption, or the product may turn off briefly (and display a power failure message). Normal product operation will resume upon restoration of the AC mains supply (the user will need to clear the power failure warning if displayed).
6. In all of the above cases, connecting the product to a different power outlet / mains circuit may resolve these issues.

II. Guidance and manufacturer's declaration – electromagnetic emissions

The PICO evo. is intended for use in the electromagnetic environment specified below. The customer or the user of the PICO evo. should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The PICO evo. uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The PICO evo. is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC61000-3-3	Complies	

III. Guidance and manufacturer's declaration – electromagnetic immunity

The PICO EVO is intended for use in the electromagnetic environment specified below. The customer or the user of the PICO EVO should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC61000-4-4	± 2 kV for power supply lines ± 1 kV for input / output lines	± 2 kV for power supply lines input / output line tests not applicable.	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5% UT (>95 % dip in UT) For 0.5 cycle 40% UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5% UT (>95 % dip in UT) For 5 s	<5% UT (>95 % dip in UT) For 0.5 cycle 40% UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5% UT (>95 % dip in UT) For 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the PICO EVO requires continued operation during power mains interruptions, it is recommended that the PICO EVO be powered from an uninterruptable power supply or a battery.
Power frequency (50Hz) Magnetic field IEC61000-4-8	3 A/m	3 A/m	If incorrect operation occurs, it may be necessary to position the PICO EVO further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the PICO evo., including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance (d)
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	d = 1.2√P
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d = 1.2√P 80 MHz to 800 MHz d = 2.3√P 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Fields strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PICO evo. is used exceeds the applicable RF compliance level above, the PICO evo. should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the PICO evo..
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

IV. Recommended separation distances between portable and mobile RF communications equipment and the PICO evo.

The PICO evo. is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PICO evo. can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PICO evo. as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 KHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures objects and people.